PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:	)	
	)	
Richard L. Dunn et al.	)	Examiner: Michael M. Thompson
	)	
Serial No.: 10/634,656	)	Group Art Unit: 3763
	)	
Filed: August 5, 2003	)	Attorney Docket: 1195.323US1
	)	
For: COUPLING SYRINGE SYSTEM AND METHODS FOR OBTAINING A MIXED COMPOSITION		

APPEAL BRIEF UNDER 37 CFR § 41.37

Mail Stop Appeal Brief- Patents
Commissioner for Patents
P.O. Box 1450
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Sir:

This Appeal Brief is presented in support of the Notice of Appeal to the Board of Patent Appeals and Interferences, filed on September 6, 2005, from the Final Rejection of claims 1-14 of the above-identified application, as set forth in the Final Office Action mailed on May 6, 2005.

The Commissioner of Patents and Trademarks is hereby authorized to charge Deposit Account No. 19-0743 in the amount of $500.00 which represents the requisite fee set forth in 37 C.F.R. § 41.2(b)(2). The Appellant respectfully requests consideration and reversal of the Examiner's rejections of pending claims 1-14.

APPEAL BRIEF UNDER 37 C.F.R. § 41.37

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1. REAL PARTY IN INTEREST

The real party in interest of the above-identified patent application is the assignee, QLT USA, INC.

2. RELATED APPEALS AND INTERFERENCES

There are no other appeals or interferences known to Appellant that will have a bearing on the Board's decision in the present appeal.

3. STATUS OF THE CLAIMS

The present application was filed on August 5, 2003 with claims 1-14. The dependency of claim 10 was amended following, but not as a result of, the Non-final Office Action mailed October 4, 2004. No claims were amended following the Final Office Action mailed May 6, 2005. Claims 1-14 stand twice rejected, remain pending, and are the subject of the present Appeal.

4. STATUS OF AMENDMENTS

No amendments have been made subsequent to the Final Office Action mailed May 6, 2005.

5. SUMMARY OF THE INVENTIVE SUBJECT MATTER

The present inventive subject matter includes, but is not limited to, systems and methods for effective mixing of compositions immediately prior to administration to a subject (e.g., a patient). (Page 6, lines 6-7).

A coupling syringe system of the present invention is identified generally by the numeral 1. (FIGS. 1-6; page 6, lines 16-17). Syringe system 1 includes a first syringe 13 and a second syringe 14. (FIGS. 1, 2, and 5; page 6, lines 17-18). The first syringe 13 includes a barrel 2 having a distal end 3, an open proximal end 4, and a wall 5 extending between the ends to define a fluid receiving chamber 6. (Page 6, lines 18-21). An outwardly projecting finger flange 7 is defined near proximal end 4 of the first syringe barrel 2 for facilitating precise manipulation of the first syringe 13. (Page 6, lines 22-24). Additionally, the distal end 3 of the first syringe barrel 2 is characterized with a tip 8. (FIG. 4; page 6, lines 24-25). The tip 8 is provided with a fluid passage 9 extending therethrough and communicating with the fluid receiving chamber 6. (Page 6, lines 25-27). The tip 8 is also provided with a male end portion 10 wherein the male end portion 10 is provided with a locking ring 11. (Page 6, lines 27-28).

The syringe system 1 also includes the second syringe 14 having a barrel 18. (FIGS. 1, 2, and 5; page 7, lines 7-8). The barrel 18 has a distal end 19, an open proximal end 20, and a wall 21 extending between the ends to define a fluid receiving chamber 22. (Page 7, lines 8-10). An outwardly projecting finger flange is defined near proximal end 20 of the second syringe barrel 18 for facilitating precise manipulation of the second syringe 14. (Page 7, lines 11-13). Additionally, the distal end 19 of the second syringe barrel is characterized with a tip 25 provided with a fluid passage 26 extending therethrough and communicating with the fluid receiving chamber 22. (FIG. 3; page 7, lines 13-16). The tip 25 is also provided with a female end portion 27 wherein the female end portion 27 is configured to detachably connect to the locking ring 11. (Page 7, lines 16-17). The female end portion 27 includes one or more exteriorly protruding members 30 adapted to detachably engage the locking ring 11.

In varying examples, the locking ring 11 is configured such that the interior of the locking ring 11 contains threads which are adapted to receive protruding members 12 exteriorly disposed on the female end portion 27 of the second syringe 14. (FIG. 3; page 6, lines 29-30; page 7, line 1). The locking ring 11 is designed to interlock the first syringe 13 (i.e., the syringe including the male end portion 10) and the second syringe 14 (i.e., the syringe including the female end portion 27). (Page 7, lines 2-4). In addition, the locking ring 11 is configured to detachably connect to a discharge assembly 15, which may include a needle 16. (FIG. 6; page 7, lines 4-6).

A plunger 40 is disposed in the fluid receiving chamber 6 and is in sliding fluid-tight engagement with the wall 5 of the syringe barrel 2. (FIGS. 1, 2, 4, and 6; page 7, lines 22-24). Sliding movement of the plunger 40 in a distal direction causes the composition (i.e., solid, liquid, or mixture thereof) in the chamber 6 to be expelled through the passage 9 of the tip 8 and into the fluid receiving chamber 22 thereby mixing the composition of chamber 6 with the composition of chamber 22. (FIGS. 1, 2, 3, 4, and 6; page 7, lines 24-28; page 8, line 1). Conversely, sliding movement of the plunger 40 in a proximal direction draws the composition in the chamber 22 through the passage 26 and into fluid receiving chamber 6 thereby mixing the composition of chamber 26 with the composition of chamber 22. (Page 8, lines 1-5).

Likewise, a plunger 90 is disposed in the fluid receiving chamber 22 and is in sliding fluid-tight engagement with the wall 21 of the syringe barrel 18. (FIGS. 1, 2, 3, and 6; page 8, lines 9-11). Sliding movement of the plunger 90 in a distal direction causes the composition in the chamber 22 to be expelled through the passage 26 of the tip 25 and into the fluid receiving chamber 6 thereby mixing the composition of chamber 22 with the composition of chamber 6. (FIGS. 1, 2, 4, and 6; page 8, lines 11-16). Conversely, sliding movement of the plunger 90 in a proximal direction draws the composition in the chamber 6 through passage 9 and into the fluid receiving chamber 22 thereby mixing the composition of chamber 6 with the composition of chamber 22. (Page 8, lines 16-20).

As discussed, the discharge assembly 15 can be connected to the locking ring 11 of the first syringe 13. (FIG. 6, page 8, lines 23-24). In one example, the discharge assembly 15 includes a needle cannula 50 having a proximal end 51, a sharp distal end 52 and a lumen 55 extending therebetween. (Page 8, lines 24-26). In such an example, a hub 75 may be joined to the cannula 50 so that the lumen 55 is in fluid communication with the hub 75. (Page 8, lines 26-27). The tip 8 (of first syringe 13) fits into the hub 75 and frictionally engages the same so that the lumen 55 of the needle cannula 50 communicates with passage through tip 8 and further communicates with fluid receiving chamber 6 of syringe barrel 2. (Page 8, lines 26-28; page 9, lines 1-2).

The first syringe 13 and the second syringe 14 can conveniently be manufactured by any suitable process, such as an injection molding process where each syringe is made as one unit. (Page 9, lines 22-25; page 10, lines 4-7). Alternatively, the first syringe 13 can be manufactured by independently molding the syringe and locking ring 11 and then mounting (i.e., attaching) the locking ring and first syringe.

Each composition to be combined with the coupling syringe system 1 can independently be a solid, liquid, or mixture thereof and include one or more compounds. (Page 10, lines 8-10 and 14-15). In addition, the compound of the composition can be a drug delivery system, a drug (i.e., pharmaceutical) or a pharmaceutically acceptable salt thereof, a liquid carrier, a liquid, a lipid formulation, or a vaccine. (Page 10, lines 15-28; page 11, lines 1-21). One example of a suitable drug delivery system includes, but is not limited to, the Atrigel® delivery system mixed with doxycycline or leuprolide acetate. (Page 10, lines 18-20).

Advantageously, the coupling syringe system of the invention allows for controlled mixing of a composition without a significant loss of the same. (Page 6, lines 7-8; page 11, lines 24-28; page 12, lines 1-27; page 13, lines 1-6; chart on page 14; page 15, lines 1-26; page 16, lines 1-4; chart on page 17). In addition, the time between the mixing and the administration of the composition is minimal, such that a sensitive composition is not chemically or physically altered. (Page 6, lines 8-12). The use of the coupling syringe system does not result in a plug

flow of contents nor do such contents need to be aspirated out of the system subsequent to mixing. (Page 6, lines 12-13). Furthermore, the coupling syringe system can conveniently be disassembled and a needle can conveniently be attached to the syringe which includes a male end portion and a locking ring. (Page 6, lines 13-15).

Notably, the page and line numbers enumerated above provide reference as to where support for such subject matter can be found in the Applicants' application as filed, however, support for such subject matter may also be found elsewhere in the application.

6. GROUNDS OF REJECTION TO BE REVIEWED ON APPEAL

Claims 1-14 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Chu (U.S. Patent No. 4,743,229) in view of Kanno (U.S. Patent No. 4,629,455).

7. ARGUMENT

A) The Applicable Law under 35 U.S.C. § 103 –

The Examiner has the burden under 35 U.S.C. § 103 to establish a *prima facie* case of obviousness. *In re Fine*, 837 F.2d 1071, 1074, 5 U.S.P.Q.2d 1596, 1598 (Fed. Cir. 1988). "If the examination at the initial stage does not produce a *prima facie* case of unpatentability, then without more the applicant is entitled to grant of the patent." *In re Oetiker*, 977 F.2d 1443, 24 U.S.P.Q.2d 1443 (Fed. Cir. 1992). A *prima facie* case requires, among other things, establishing each of the following.

a. Cited references must teach the invention, which is to be considered as a whole (i.e., its structure, its properties, and the problem it solves).

According to M.P.E.P. § 2142, the prior art reference (or references) must teach or suggest *all* of the claim limitations. (Emphasis added). Similarly, the Federal Circuit has stated that the prior art reference (or references) must disclosure each element of the claimed invention "*arranged as in the claim.*" *Lindermann Maschinenfabrik GmbH v. American Hoist & Derrick Co.*, 730 F.2d 1452, 221 U.S.P.Q. 481, 485 (Fed. Cir. 1984)(citing *Connell v. Sears, Roebuck & Co.*, 722 F.2d 1542, 220 U.S.P.Q. 193 (Fed. Cir. 1983))(emphasis added).

If the prior art reference contains a different structure from the claimed invention, the reference might not be considered an equivalent of the claim invention to support an obviousness rejection. *Warminster Fiberglass Co. v. Delta Fiberglass Structures, Inc.* is an example of when a device had a different structure and was therefore not considered an equivalent of the claimed invention. According to the Federal Circuit:

> [i]n this case, the inventors specifically claimed a scum baffle that was integral with the hood. Because we interpret the term integral to mean "structurally related," we cannot consider the accused device, in which the scum baffle and hood are physically separated, to be the equivalent of the claimed invention without reading out the term "integral."

42 U.S.P.Q.2d 1154 (Fed. Cir. 1996)(unpublished). Similarly, if the prior art reference performs

in a different way and provides different results, the reference may not be considered an equivalent of the claimed invention to support an obviousness rejection. *See Lehman v. Duhman's Athleisure Corp.*, Civ. App. No. 96-1381 (Fed. Cir. Oct. 11, 1996)(unpublished).

In addition, the validity of a claim is determined on the basis of the subject matter of the claim as a whole. *Panduit Corp. v. Dennison Mfg. Co.*, 774 F.2d 1082, 227 U.S.P.Q. 337 (Fed. Cir. 1985), *remanded*, 475 U.S. 809, 229 U.S.P.Q. 478 (1986), *on remand*, 810 F.2d 1561, 1 U.S.P.Q.2d 1593 (Fed. Cir. 1987), *cert. denied*, 481 U.S. 1052 (1987). "[I]t is the invention as a whole that must be considered in obviousness determinations. The invention as a whole embraces the structure, its properties, and the problem it solves." *In re Wright*, 848 F.2d 1216, 6 U.S.P.Q.2d 1959 (Fed. Cir. 1988); *see also Interconnect Planning Corp. v. Feil*, 774 F.2d 1132, 1143, 227 U.S.P.Q. 543, 551 (Fed. Cir. 1985).

The Federal Circuit has adopted the view that discovery of the problem is significant in determining obviousness and has stated the following:

> Nowhere in the statute or the constitution is the patent system opened only to those who make complex inventions difficult for judges to understand and foreclosed to those who make less mysterious inventions a judge can understand after hearing, as here, the inventor's explanation of his invention and the engineering principles he employed. The constitutional purpose is to encourage disclosure of patentable contributions to "progress in the useful arts," *all* the useful arts, not just the esoteric. The statute requires utility, novelty, and nonobviousness, not complexity.

Panduit Corp., 810 F.2d at 1561, 1 U.S.P.Q.2d at 1600.

b. Suggestion to combine or modify the references is required.

According to *In re Lee*, "there must be some motivation, suggestion, or teaching of the desirability of making the specific combination that was made by the applicant." 61 U.S.P.Q.2d 1430 (Fed. Cir. 2002). The "factual question of motivation is material to patentability, and [can] not be resolved on subjective belief and unknown authority." *Id.* "Obviousness cannot be established by combining the teachings of the prior at to produce the claimed invention, absent some teaching[,] suggestion[,] or incentive supporting the combination." *In re Geiger*, 815 F.2d

686, 2 U.S.P.Q.2d 1276, 1278 (Fed. Cir. 1987). A factor cutting against a finding of motivation to combine or modify the prior art is when the prior art teaches away from the claimed combination. *See In re Gurley*, 27 F.3d 551, 31 U.S.P.Q.2d 1130, 1131 (Fed. Cir. 1994).

Motivation to combine references requires desirability, not merely trade-offs. Trade-offs often concern what is feasible, not what is necessarily desirable. Motivation requires the latter. *Winner International Royality Corp. v. Wang*, 202 F.3d 1340, 53 U.S.P.Q.2d 1580 (Fed. Cir.), *cert. denied*, 530 U.S. 1238 (2000)

Additionally, the suggestion or motivation must exist before the date of invention. 35 U.S.C. § 103(a) ("differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole *would have been* obvious at the time the invention was made")(emphasis added). Thus, it is incorrect for the Examiner to formulate the suggestion or motivation based on current knowledge; the Examiner must remove all knowledge that he or she has accumulated since the date of invention. *Panduit Corp.*, 810 F.2d at 1561, 1 U.S.P.Q.2d at 1596-96. Hindsight must be avoided by the Examiner. *In re Bond*, 910 F.2d 831, 834, 15 U.S.P.Q.2d 1566, 1568 (Fed. Cir. 1990).

B) Discussion of the Rejection of Claims 1-14 under 35 U.S.C. § 103(a) as being unpatentable over Chu (U.S. Patent No. 4,743,229) in view of Kanno (U.S. Patent No. 4,629,455) –

Claims 1-14 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Chu in view of Kanno. Applicant respectfully traverses the rejection and submits that the Final Office Action (FOA) has failed to establish a *prima facie* case of obviousness on at least the following grounds.

a. The cited references, neither alone nor in combination, teach or suggest all the limitations of the claims.

Both the Non-final office action (NFOA) mailed October 4, 2004 and the Final Office Action (FOA) mailed May 6, 2005 assert that "Chu teaches all of the limitations of the claims except for explicitly reciting the locking ring being rotatable coupled with the male end portion."

(NFOA, pages 2-3; FOA, page 2). It is further asserted that "Kanno teaches a rotatably coupled locking ring mounted on a medical instrument." (*Id.*). Contrary to the position taken by such office actions, the Applicants cannot find in Chu (nor Kanno):

> a first syringe including a first syringe barrel having a first syringe open proximal end and a first syringe distal end, *the first syringe further including a first syringe tip with a male end portion wherein the male end portion has a locking ring and a tip*, . . . a second syringe including a second syringe barrel having a second syringe open proximal end and a second syringe distal end, *the second syringe further including a second syringe tip with a female end portion wherein the female end portion comprises one or more exteriorly protruding members adapted to detachably fit the locking ring*, . . . *the female end portion having an opening therein, the opening sized and configured to receive the tip of the male end portion therein*; *wherein the locking ring couples the first syringe to the second syringe when the tip of the male end portion is disposed within the female end portion, forming a fluid tight engagement*,

as recited in Applicants' claim 1. (Emphasis added). Unlike the claimed invention, Chu recites a separate connector means 50 which is used to connect a first syringe 12 to a second syringe 14. (Chu, col. 3, lines 35-37; col. 4, lines 25-27 and 44-59; col. 6, lines 19-20 and 45-47; FIG. 2). FIG. 2 clearly illustrates that the connection means 50 is an element not integrated with either the first syringe 12 or the second syringe 14 (i.e., an element separate from both the first syringe 12 and the second syringe 14). (*See* Chu, FIG. 2).

The FOA implicitly recognizes that, unlike Chu, the Applicants claimed invention does not require a separate connection element to be positioned between the syringes to establish a connection therebetween. To this end, however, the FOA takes the position that "Applicant recites a coupling syringe system *comprising*, making suitable the existence and use of the additional connection element." (FOA, pp. 3)(emphasis in original). The Applicants assert that the foregoing position fails in establishing a *prima facie* case of obviousness on at least three grounds.

First, although the open transitional phrase "comprising" is used allowing for the inclusion of a separate connection element, all the limitations of Applicants' claim 1 remain unmet by the cited references as required by M.P.E.P. § 2142. Specifically, neither Chu nor

Kanno recites, for example, "a first syringe including . . . a first syringe tip with a male end portion wherein the male end portion has a locking ring and a tip . . . a second syringe including . . . a second syringe tip with a female end portion wherein the female end portion comprises one or more exteriorly protruding members adapted to detachably fit the locking ring . . . the female end portion having an opening therein, the opening sized and configured to receive the tip of the male end portion therein; wherein the locking ring couples the first syringe to the second syringe when the tip of the male end portion is disposed within the female end portion."

Second, the addition of a separate connection element to be positioned between the syringes to establish a connection is not in concert with the Applicants' invention as a whole, as required by *In re Wright*, 848 F.2d 1216, 6 U.S.P.Q.2d 1959. As one example, the Applicants' invention provides a solution to a problem of mixing systems including two syringes with an independent coupling means (i.e., a system similar to Chu). (Applicants' Application, pp. 2, lns. 1-9; pp. 4, lns. 1-9; pp. 6, lns. 6-15). Specifically, the Applicants state in their application:

> "[t]he present invention provides a syringe system wherein components of a composition can be easily mixed by the end user without losing a significant amount of mixed composition during the mixing process and wherein the mixed composition can be easily and rapidly administered to a patient. The syringe system has a relatively few number of interconnecting parts, to minimize human error and to minimize sample loss. Additionally, the syringe system effectively mixes the contents located therein without sample loss, such that it can be approved by the FDA when used with drugs that must be administered in a known, discrete and precise amount (e.g., leuprolide acetate)."

(*Id.*, pp. 4, lns. 12-20). Moreover, the Applicants state that "[t]he use of the coupling syringe system of the invention does not result in a plug flow of contents . . . [and] can conveniently be disassembled and a needle can conveniently be attached to the syringe which includes a male end portion and a locking ring." (*Id.*, pp. 6, lns. 12-15). The Applicants recognition of the above-identified (prior art) problems is significant and, according to *Panduit*, must be considered in any obviousness determination. 810 F.2d 1561, 1 U.S.P.Q. 1593.

Third, the structure of the Applicants' coupling syringe system differs from the structures recited in the cited references, which – in light of the similar facts and Federal Circuit's holding

in *Warminster Fiberglass Co.*, 42 U.S.P.Q.2d 1154 – provides another ground combating a finding of obviousness in the present case. For instance, the Applicants' invention (unlike Chu) does not require a separate connection element to be positioned between the syringes to establish a connection. Specifically, the Applicants' application states that "syringe system 1 includes a first syringe 13 and a second syringe 14[,] . . . first syringe 13 includes a barrel 2 . . . ha[ving] a distal end 3 . . . [which] is characterized with a tip 8[,] . . . tip 8 is [ ] provided with a male end portion 10 wherein the male end portion 10 is provided with a locking ring 11[;] . . . second syringe 14 ha[s] a barrel 18 . . . ha[ving] a distal end 19 . . . [which] is characterized with a tip 25[,] . . . tip 25 [ ] is provided with a female end portion 27 wherein the female end portion 27 is configured to detachably connect to the locking ring 11." (*Id.*, pp. 6, lns. 16-28; pp. 7, lns. 7-21).

The FOA further takes the position that it "may rely on the connection piece [50] in combination with the first syringe to constitute a male/female end of the connection piece combination for connection to the second syringe when applying the broadest possible interpretation of the claim." (FOA, pp. 3). The Applicants assert that such position also fails to make out (i.e., establish) a *prima facie* case of obviousness on a number of grounds.

First, as applied to Chu, "the connection piece [50] in combination with the first syringe [12] . . . for connection to the second syringe [14]" does not meet all the limitations of Applicants' claim 1. As one example, the connection piece [50]/first syringe [12] combination does not meet the limitation "the first syringe . . . including a first syringe tip with a male end portion wherein the male end portion has a locking ring and a tip," as recited in Applicants' claim 1. As another example, the connection piece [50]/first syringe [12] combination does not meet the limitation "the second syringe . . . including a second syringe tip with a female end portion wherein the female end portion comprises one or more exteriorly protruding members adapted to detachably fit the locking ring," as further recited in Applicants' claim 1.

Second, "the connection piece [50] in combination with the first syringe [12] . . . for connection to the second syringe [14]" is not in concert with the Applicants' invention as a whole, such as the invention's properties, as required by *In re Wright.* 848 F.2d 1216, 6

U.S.P.Q.2d 1959. As one example, the direct detachable connection between the first and second syringes of the Applicants' claimed invention importantly allows for the forming of a mixed composition without "result[ing] in a significant loss of the composition." (Applicants' Application, pp. 6, lns. 7-8). This property/characteristic is especially important when mixing drug compositions, such as leuprolide acetate, that are closely regulated by the Food and Drug Administration (FDA). Even very small amounts of leakage of leuprolide acetate would be troubling for at least two reasons. First, any leakage would result in waste of an expensive drug. Second (and more importantly), because leuprolide acetate is a potent drug that must be administered in a narrow dosage range, the FDA would not approve a device for its mixing or delivery that resulted in a delivery of an uncertain amount of the drug. Other drugs that the Applicants' direct coupling syringe system is intended to mix may also have the characteristics of being expensive and/or having a dosage closely regulated by the FDA. To be used with these drugs, the coupling syringe system must not result in a significant loss/leak.

Unlike the Applicants' invention (which results in a minimal trapped content in the hub of the first syringe including the male end portion – see Applicants' Application, pages 12 and 15), the connection piece [50]/first syringe [12] combination suggested by the FOA results in a fluid pathway extending from at least end ridge 52 to end ridge 54 (i.e., two male end portion hubs plus a space within connector 50, *see* Chu, FIGS. 1-3), the entire contents of which must be aspirated out of the pathway or they will be lost. As discussed above, the plug flow of contents is one of the problems that the Applicants' claimed invention was made to solve. Notably, the plug flow of contents does not appear to be a concern in Chu. As one example, Chu states that "[a] preferred ratio of collagen dispersion to mineral [(i.e., the two compositions to be mixed in Chu)] is about 1:1 by weight, *but ratios as high as about 4:1 are acceptable.*" (Chu, col. 5, lns. 23-25)(emphasis added). In other words, the necessity for precision as to the ratio of the compositions to be mixed is lacking in Chu.

Claims 2-14 are dependent on claim 1 and are patentable over Chu in view of Kanno for the reasons argued above, plus the elements in such claims.

b. There is no suggestion to modify or combine the cited references.

Applicants cannot find any motivation, suggestion, or teaching to combine the teachings of Chu with the teachings of Kanno to make the specific combination that was made by Applicants, as required by *In re Lee*. Specifically, Applicants cannot find in Chu any motivation, suggestion, or teaching to combine the teachings therein with the teachings of Kanno for the purpose of creating "a first syringe including . . . a first syringe tip with a male end portion wherein the male end portion has a locking ring . . . the female end portion having an opening therein, the opening sized and shaped to receive the tip of the male end portion; wherein the locking ring couples the first syringe to [a] second syringe when [a] tip of the male end portion is disposed within [a] female end portion, forming a fluid tight engagement," as recited in Applicants' claim 1.

The FOA acknowledges that Chu provides no such motivation, suggestion, or teaching, but states that "[i]t would have been obvious to one of ordinary skill in the art, at the time of invention to have modified the connecting structure of Chu with the connecting member as taught by Kanno for the well known purpose of providing a male and female connection alternative that can be joined firmly with high reliability." (FOA, pp. 2). Applicants submit that this is an unsupported assertion, as prohibited by *In re Lee*. It is respectfully submitted that the above-identified assertion amounts to a form of Official Notice, which is timely traversed herein under M.P.E.P. § 2144.03, and if the Examiner is aware of a reference providing support for the assertion, citation of such reference is respectfully requested. If a reference cannot be provided, Applicants submit the assertion is formed on the personal knowledge of the Examiner, and Applicants request that an affidavit is provided, as required by 37 C.F.R. § 1.104(d), or removal of this 35 U.S.C. § 103 basis of rejection. Applicants further submit that the combination of Chu and Kanno does not meet the desirability threshold as required by *Winner International Royality Corp.*, 202 F.3d 1340, 53 U.S.P.Q.2d 1580. Rather, Applicants submit that such combination merely meets the trade-off threshold.

Moreover, Applicants note that Chu recites a first adapter 42 located at an end 18 of a first syringe 12 and a second adapter 44 located at an end 24 of a second syringe 14. (Chu, col. 4, lns. 45-48). Chu states that "these adapters are preferably male Luer connectors which may be provided with internal threads." (*Id.*, col. 4, lns. 48-50). "The adapters are joined by connector means 50 which is preferably a female Luer connector. End ridges 52 and 54 of the female Luer connector are adapted to fit within the threads 46 and 48 of the male Luer connector." (*Id.*, col. 4, lns. 50-54). Chu further recites an alternative embodiment in which "threads 46 and 48 may be replaced by an internal groove which provides a 'snap'-type connection with female Luer connector 50." (*Id.*, col. 4, lns. 55-57). In sum, Chu recites two connection schemes that may join (in fluid communication) a first device to a second device and makes no mention of a need for additional connection alternatives. Accordingly, one of ordinary skill in the art would have had no reason to consider additional connection alternatives to make a connection between two devices, such as a first syringe and a second syringe or discharge assembly. Rather, one of ordinary skill would have appreciated the desirability of the Applicants' claimed invention, including a male/female connection utilizing a syringe integrated locking ring to join a first syringe to a second syringe or discharge assembly, only upon access to the Applicants' disclosure which is impermissible.

Further yet, Applicants submit that Chu teaches away from being combined with, and/or modified in light of, Kanno. As one example, Chu recites that an object of the invention contained therein is structural simplicity and being inexpensive to construct. (Chu, col. 2, lines 58-60). Kanno, on the other hand, recites a "rib in the threaded groove is placed into engagement with the threaded ridge by being deformed upon helical engagement with the threaded ridge." (Kanno, col. 3, lines 39-42). Kanno further recites that "because of the limited thickness [i.e., 0.15 to 1.50 mm], the rib 22 is fractured relatively easily by the threaded ridge 23 and the necessary frictional force is obtained between the fractured rib 22 and the threaded ridge 23." (*Id.*, col. 5, lines 24-27; col. 7, lines 28-33). That is, Kanno (in opposition to the objectives of Chu) recites a rib requiring precise (and thus manufacturably expensive) tolerancing.

Because the FOA has not established a proper *prima facie* case of obviousness, Applicants respectfully request reversal of the 35 U.S.C. § 103(a) rejections of claims 1-14.

8. SUMMARY

For the reasons argued above, Applicants submit that claims 1-14 were not properly rejected under 35 U.S.C. § 103(a) as being unpatentable over Chu in view of Kanno.

It is respectfully submitted that the art cited does not render the claims obvious and that the claims are patentable over the cited art. Reversal of the rejections and allowance of the pending claims are respectfully requested.

Respectfully submitted,

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CERTIFICATE UNDER 37 CFR 1.8: The undersigned hereby certifies that this correspondence is being deposited with the United States Postal Service with sufficient postage as first class mail, in an envelope addressed to: Mail Stop Appeal Brief, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450, on this 7th day of November, 2005.

Dawn M. Poole
Name

Dawn M. Poole
Signature

CLAIMS APPENDIX

The Claims on Appeal

1. (Original) A coupling syringe system comprising:

a first syringe including a first syringe barrel having a first syringe open proximal end and a first syringe distal end, the first syringe further including a first syringe tip with a male end portion wherein the male end portion has a locking ring and a tip, the first syringe barrel having a first syringe inner surface;

a first syringe plunger slidably disposed within the first syringe barrel, the first syringe plunger in fluid-tight engagement with the first syringe inner surface;

a second syringe including a second syringe barrel having a second syringe open proximal end and a second syringe distal end, the second syringe further including a second syringe tip with a female end portion wherein the female end portion comprises one or more exteriorly protruding members adapted to detachably fit the locking ring, the second syringe barrel having a second syringe inner surface;

a second syringe plunger slidably disposed within the second syringe barrel, the second syringe plunger in fluid-tight engagement with the second syringe inner surface;

the female end portion having an opening therein, the opening sized and configured to receive the tip of the male end portion therein;

wherein the locking ring couples the first syringe to the second syringe when the tip of the male end portion is disposed within the female end portion, forming a fluid tight engagement.

2. (Original) The coupling syringe system of claim 1 wherein the female end portion comprises one or more exteriorly protruding members adapted to detachably engage the locking ring.

3. (Original) The coupling syringe system of claim 1 wherein the locking ring is configured to detachably connect to a discharge assembly.

4. (Original) The coupling syringe system of claim 3 wherein the discharge assembly comprises a needle.

5. (Original) The coupling syringe system of claim 1 wherein the female end portion of the second syringe is detachably connected to the male end portion of the first syringe via the locking ring.

6. (Original) The coupling syringe system of claim 1 wherein the female end portion of the second syringe is detached from the male end portion of the first syringe.

7. (Original) The coupling syringe system as recited in claim 1, further comprising an outwardly projecting flange near the first syringe proximal end.

8. (Original) The coupling syringe system as recited in claim 1, further comprising an outwardly projecting flange near the second syringe proximal end.

9. (Original) The coupling syringe system as recited in claim 1, wherein the locking ring is rotatably coupled with the male end portion.

10. (Previously Presented) The coupling syringe system as recited in claim 1, wherein the locking ring is threadingly coupled with one or more projections disposed on an outer surface of the female end portion.

11. (Original) The coupling syringe system as recited in claim 1, wherein the male end is disposed within the female end.

12. (Original) The coupling syringe system as recited in claim 1, wherein the locking ring is rotatably coupled with the male end portion and the locking ring is threadingly coupled with one or more projections disposed on an outer surface of the female end portion.

13. (Original) The coupling syringe system as recited in claim 1, wherein at least one of the first and second syringes contains therein a composition including a drug delivery system.

14. (Original) The coupling syringe system as recited in claim 13, wherein the other syringe contains therein a drug.

EVIDENCE APPENDIX

None.

RELATED PROCEEDINGS APPENDIX

None.

AF/DFW

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant: Richard L. Dunn et al.

Title: COUPLING SYRINGE SYSTEM AND METHODS FOR OBTAINING A MIXED COMPOSITION

Docket No.:	1195.323US1	Serial No.:	10/634,656
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